

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

NI *et al.*

Appl. No.: *To be assigned* (Continuation of  
Appl. No. 09/874,138; Filed: June 6, 2001)

Filed: February 5, 2004

For: **Death Domain Containing Receptor 5**

Confirmation No.: *To be assigned*

Art Unit: *To be assigned*

Examiner: *To be assigned*

Atty. Docket: 1488.131000D/EKS/EJH/ SJE

**Information Disclosure Statement**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

The Examiner's attention is directed to the following co-pending U.S. Patent Applications, which are directed to related technical subject matter:

U.S. Patent Application No. 09/042,583, filed March 17, 1998, listed herewith as Document AT7; and

U.S. Patent Application No. 09/565,009, filed May 4, 2000, listed herewith as Document AR8.

Applicants wish to bring to the attention of the Examiner that SEQ ID NO:1 and the corresponding cDNA clone of this application are related to SEQ ID NOs: 7851 and 190763 in copending U.S. Patent Application No. 09/912,293. A copy of that portion of U.S. Patent Application No. 09/912,293 which caused it to be listed on the attached Form PTO-1449 is listed herewith as Document AS8.

Applicants wish to direct the Examiner's attention to the following documents:

Statement of Grounds and Particulars filed in opposition to Human Genome Sciences, Inc., Australian Patent Application 747635 (67635/98) by Genentech, Inc; and

Statutory Declaration of Avi Ashkenazi, signed March 14, 2003, with Exhibits AJA1 to AJA3, AJA5, and AJA7 to AJA10.

Exhibit AJA-4 is listed as Document AO3, Exhibit AJA-6 is listed as Document AT3. The above-listed documents were brought to the attention of the Applicants in connection with an opposition to an Australian application that essentially corresponds to the U.S. priority application in this case. A copy of the above-listed documents, exclusive of documents cited elsewhere, are listed on the attached Form PTO-1449 as Documents AC2, and AT11 to AT14.

Copies of the cited documents were cited by or submitted to the Office in Information Disclosure Statements that comply with 37 C.F.R. § 1.98(a)-(c) in Application No. 09/874,138, filed June 6, 2001, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d).

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached Form PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed Form PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

*Frank R. Collighan*

Reg. No. 50,437

For: Elizabeth J. Haanes, Ph.D.  
Attorney for Applicants  
Registration No. 42,613

Date: February 10, 2004  
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(202) 371-2600

FORM PTO-1449

INFORMATION DISCLOSURE STATEMENTATTY. DOCKET NO.  
1488.131000D/EKS/EJH/SJEAPPLICATION NO.  
*To be assigned*FIRST NAMED INVENTOR  
Jian NIFILING DATE  
February 10, 2004ART UNIT  
*To be assigned***U.S. PATENT DOCUMENTS**

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA1	4,002,531	01/11/1977	Royer	195	68	01/22/1976
	AB1	4,946,778	08/07/1990	Ladner <i>et al.</i>	435	69.6	01/19/1989
	AC1	5,349,053	09/20/1994	Landolfi	530	351	06/10/1993
	AD1	5,447,851	09/05/1995	Beutler <i>et al.</i>	435	69.7	04/02/1992
	AE1	5,478,925	12/26/1995	Wallach <i>et al.</i>	530	351	08/07/1992
	AF1	5,530,101	06/25/1996	Queen <i>et al.</i>	530	387.3	12/19/1990
	AG1	5,565,332	10/15/1996	Hoogenboom <i>et al.</i>	435	69.1	09/23/1994
	AH1	5,643,575	07/01/1997	Martinez <i>et al.</i>	424	194.1	10/27/1993
	AI1	5,763,223	06/09/1998	Wiley <i>et al.</i>	435	69.5	06/25/1996
	AJ1	5,807,715	09/15/1998	Morrison <i>et al.</i>	435	69.6	06/27/1994
	AK1	6,072,047	06/06/2000	Rauch <i>et al.</i>	536	23.5	06/26/1997

**FOREIGN PATENT DOCUMENTS**

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL1	EP 0 239 400 B1	09/30/1998	Europe			Yes No
	AM1	EP 0 401 384 B1	12/12/1990	Europe			Yes No
	AN1	WO 91/06570	05/16/1991	WIPO			Yes No
	AO1	WO 91/09967	07/11/1991	WIPO			Yes No
	AP1	CA 2045869	12/29/1991	Canada			Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

	AR	1	Chaudhary, P.M., <i>et al.</i> , "Death Receptor 5, a New Member of the TNFR Family, and DR4 Induce FADD-Dependent Apoptosis and Activate the NF- $\kappa$ B Pathway," <i>Immunity</i> 7:821-830, Cell Press (December 1997).
	AS	1	Chinnaiyan, A.M., <i>et al.</i> , "Signal Transduction by DR3, a Death Domain-Containing Receptor Related to TNFR-1 and CD95," <i>Science</i> 274:990-992, American Association for the Advancement of Science (November 1996).
	AT	1	Delgado, C., <i>et al.</i> , "The Uses and Properties of PEG-Linked Proteins," <i>Crit. Rev. Ther. Drug Carrier Sys.</i> 9:249-304, CRC Press, Inc. (1992).

EXAMINER

DATE CONSIDERED

**EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449  <u>INFORMATION DISCLOSURE STATEMENT</u>	ATTY. DOCKET NO. 1488.131000D/EKS/EJH/SJE	APPLICATION NO. <i>To be assigned</i>
	FIRST NAMED INVENTOR Jian Ni	
	FILING DATE February 10, 2004	ART UNIT <i>To be assigned</i>

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA2	6,313,269 B1	11/06/2001	Deen <i>et al.</i>	530	350	06/15/1999
	AB2	6,342,369 B1	01/29/2002	Ashkenazi	435	69.1	05/14/1998
	AC2	6,569,642 B1	05/27/2003	Rauch <i>et al.</i>	435	69.1	03/27/2000
	AD2						
	AE2						
	AF2						
	AG2						
	AH2						
	AI2						
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## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL2	EP 0 510 691 A1	10/28/1992	Europe			Yes No
	AM2	WO 94/01548	01/20/1994	WIPO			Yes No
	AN2	WO 95/06058	03/02/1995	WIPO			Yes No
	AO2	WO 98/32856	07/30/1998	WIPO			Yes No
	AP2	WO 98/35986	08/20/1998	WIPO			Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	2	Huston, J.S., <i>et al.</i> , "Protein Engineering of Single-Chain Fv Analogs and Fusion Proteins," <i>Meth. Enzymol.</i> 203:46-88, Academic Press, Inc. (1991).
	AS	2	Marsters, S.A., <i>et al.</i> , "A novel receptor for APO2L/Trail contains a truncated death domain," <i>Curr. Biol.</i> 7:1003-1006, Current Biology Ltd. (December 1997).
	AT	2	Morpurgo, M., <i>et al.</i> , "Covalent Modification of Mushroom Tyrosinase with Different Amphiphilic Polymers for Pharmaceutical and Biocatalysis Applications," <i>Appl. Biochem. Biotechnol.</i> 56:59-72, Humana Press Inc. (January 1996).

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	AA3						
	AB3						
	AC3						
	AD3						
	AE3						
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	AG3						
	AH3						
	AI3						
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**FOREIGN PATENT DOCUMENTS**

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL3	EP 0 870 827 A2	10/14/1998	Europe			Yes No
	AM3	WO 99/02653	01/21/1999	WIPO			Yes No
	AN3	WO 98/46643 A1	10/22/1998	WIPO			Yes No
	AO3	WO 98/51793 A1	11/19/1998	WIPO			Yes No
	AP3	WO 99/00423 A1	01/07/1999	WIPO			Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

	AR	<u>3</u>	Morrison, S.L., "Transfectomas Provide Novel Chimeric Antibodies," <i>Science</i> 229:1202-1207, American Association for the Advancement of Science (1985).
	AS	<u>3</u>	Pan, G., <i>et al.</i> , "The Receptor for the Cytotoxic Ligand TRAIL," <i>Science</i> 276:111-113, American Association for the Advancement of Science (April 1997).
	AT	<u>3</u>	Pan, G., <i>et al.</i> , "An Antagonist Decoy Receptor and a Death Domain-Containing Receptor for TRAIL," <i>Science</i> 277:815-818, American Association for the Advancement of Science (August 1997).

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA4						
	AB4						
	AC4						
	AD4						
	AE4						
	AF4						
	AG4						
	AH4						
	AI4						
	AJ4						
	AK4						

**FOREIGN PATENT DOCUMENTS**

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL4						Yes No
	AM4						Yes No
	AN4						Yes No
	AO4						Yes No
	AP4						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

AR	<u>4</u>	Rieger, J., <i>et al.</i> , "APO2 ligand: a novel lethal weapon against malignant glioma?" <i>FEBS Lett.</i> 427:124-128, Federation of European Biochemical Societies (May 1998).
AS	<u>4</u>	Roguska, M.A., <i>et al.</i> , "Humanization of murine monoclonal antibodies through variable domain resurfacing," <i>Proc. Natl. Acad. Sci. USA</i> 91:969-973, National Academy of Sciences (1994).
AT	<u>4</u>	Schneider, P., <i>et al.</i> , "TRAIL Receptors 1 (DR4) and 2 (DR5) Signal FADD-Dependent Apoptosis and Activate NF- $\kappa$ B," <i>Immunity</i> 7:831-836, Cell Press (December 1997).

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA5						
	AB5						
	AC5						
	AD5						
	AE5						
	AF5						
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**FOREIGN PATENT DOCUMENTS**

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL5						Yes No
	AM5						Yes No
	AN5						Yes No
	AO5						Yes No
	AP5						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

	AR	<u>5</u>	Sheikh, S.M., <i>et al.</i> , "p53-dependent and -independent Regulation of the Death Receptor <i>KILLER/DR5</i> Gene Expression in Response to Genotoxic Stress and Tumor Necrosis Factor $\alpha$ ," <i>Cancer Res.</i> 58:1593-1598, American Association for Cancer Research (April 1998).
	AS	<u>5</u>	Sheridan, J.P., <i>et al.</i> , "Control of TRAIL-Induced Apoptosis by a Family of Signaling and Decoy Receptors," <i>Science</i> 277:818-821, American Association for the Advancement of Science (August 1997).
	AT	<u>5</u>	Uhlén, M., <i>et al.</i> , "Fusion proteins in biotechnology and structural biology," <i>Curr. Opin. Biotechnol.</i> 3:363-369, Current Biology Ltd. (1992).

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA6						
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**FOREIGN PATENT DOCUMENTS**

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL6						Yes No
	AM6						Yes No
	AN6						Yes No
	AO6						Yes No
	AP6						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

	AR	<u>6</u>	Wiley, S.R., <i>et al.</i> , Identification and Characterization of a New Member of the TNF Family that Induces Apoptosis," <i>Immunity</i> 3:673-682, Cell Press (1995).
	AS	<u>6</u>	Zamai, L., <i>et al.</i> , "Natural killer (NK) Cell-mediated Cytotoxicity: Differential Use of TRAIL and Fas Ligand by Immature and Mature Primary Human NK Cells," <i>J. Exp. Med.</i> 188:2375-2380, Rockefeller University Press (December 1998).
	AT	<u>6</u>	NCBI Entrez, Genbank Report, Accession No. Z66083, from MacDonald, M., <i>et al.</i> (October 1995).

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA7						
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**FOREIGN PATENT DOCUMENTS**

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL7						Yes No
	AM7						Yes No
	AN7						Yes No
	AO7						Yes No
	AP7						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

	AR	<u>1</u>	NCBI Entrez, Genbank Report, Accession No. AA223122, from Hillier, L., <i>et al.</i> (February 1997).
	AS	<u>1</u>	NCBI Entrez, Genbank Report, Accession No. AA232440, from Hillier, L., <i>et al.</i> (February 1997).
	AT	<u>1</u>	Pending Non-Provisional United States Patent Application No.09/042,583, Ni <i>et al.</i> , filed March 17, 1998.

EXAMINER

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA8						
	AB8						
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**FOREIGN PATENT DOCUMENTS**

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL8						Yes No
	AM8						Yes No
	AN8						Yes No
	AO8						Yes No
	AP8						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

AR	<u>8</u>	Pending Non-Provisional United States Patent Application No. 09/565,009, Ni <i>et al.</i> , filed May 4, 2000.
AS	<u>8</u>	Pending Non-Provisional U.S. Patent Application No. 09/912,293, filed July 26, 2001, NOT PUBLISHED: pages 1-75 (pages 1 + 2 partially redacted); portion of Table 2; and SEQ ID NOs.: 7851 and 190763.
AT	<u>8</u>	Beutler, B., and Cerami, A., "Tumor Necrosis, Cachexia, Shock, and Inflammation: A Common Mediator," <i>Ann. Rev. Biochem.</i> 57:505-518, Annual Reviews Inc. (1988).

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA9						
	AB9						
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**FOREIGN PATENT DOCUMENTS**

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL9						Yes No
	AM9						Yes No
	AN9						Yes No
	AO9						Yes No
	AP9						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

AR	<u>9</u>	Fiers, W., "Tumor necrosis factor. Characterization at the molecular, cellular and in vivo level," <i>FEBS Lett.</i> 285:199-212, Elsevier Science B.V. (1991).
AS	<u>9</u>	Goeddel, D.V., <i>et al.</i> , "Tumor Necrosis Factors: Gene Structure and Biological Activities," <i>Cold Spring Harb. Symp. Quant. Biol.</i> 51(Pt. 1):597-609, Cold Spring Harbor Laboratory Press (1986).
AT	<u>9</u>	Golstein, P., "Cell death: TRAIL and its receptors," <i>Curr. Biol.</i> 7:R750-R753, Current Biology Ltd. (December 1997).

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	AA10						
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**FOREIGN PATENT DOCUMENTS**

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	AL10						Yes No
	AM10						Yes No
	AN10						Yes No
	AO10						Yes No
	AP10						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

AR	<u>10</u>	Gruss, H.-J., and Dower, S.K., "Tumor Necrosis Factor Ligand Superfamily: Involvement in the Pathology of Malignant Lymphomas," <i>Blood</i> 85:3378-3404, The American Society of Hematology (1995).
AS	<u>10</u>	Locksley, R.M., <i>et al.</i> , "The TNF and TNF Receptor Superfamilies: Integrating Mammalian Biology," <i>Cell</i> 104:487-501, Cell Press (February 2001).
AT	<u>10</u>	Nagata, S., "Apoptosis by Death Factor," <i>Cell</i> 88:355-365, Cell Press (February 1997).

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA11						
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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
							Yes No
	AL11						Yes No
	AM11						Yes No
	AN11						Yes No
	AO11						Yes No
	AP11						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

AR	<u>11</u>	Old, L.J., "Tumor Necrosis Factor," <i>Scientific American</i> , pp. 59-75, Scientific American, Inc. (May 1988).
AS	<u>11</u>	Wallach, D., "TNF Ligand and TNF/NGF Receptor Families," in <i>Cytokine Reference. A compendium of cytokines and other mediators of host defense</i> , Oppenheim, J.J., et al., eds., Academic Press, Inc., San Diego, CA, pp. 377-411 (August 2000).
AT	<u>11</u>	Brojatsch, J., et al., "CAR1, a TNFR-Related Protein, Is a Cellular Receptor for Cytopathic Avian Leukosis-Sarcoma Viruses and Mediates Apoptosis," <i>Cell</i> 87:845-855, Cell Press (November 1996).

EXAMINER

DATE CONSIDERED

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FORM PTO-1449

INFORMATION DISCLOSURE STATEMENTATTY. DOCKET NO.  
1488.131000D/EKS/EJH/SJEAPPLICATION NO.  
*To be assigned*FIRST NAMED INVENTOR  
Jian NiFILING DATE  
February 10, 2004ART UNIT  
*To be assigned***U.S. PATENT DOCUMENTS**

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA12						
	AB12						
	AC12						
	AD12						
	AE12						
	AF12						
	AG12						
	AH12						
	AI12						
	AJ12						
	AK12						

**FOREIGN PATENT DOCUMENTS**

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL12						Yes No
	AM12						Yes No
	AN12						Yes No
	AO12						Yes No
	AP12						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

	AR	<u>12</u>	Chapman, B.S., "A region of the 75 kDa neurotrophin receptor homologous to the death domains of TNFR-I and Fas," <i>FEBS Lett.</i> 374:216-220, Elsevier (1995).
	AS	<u>12</u>	Rabizadeh, S., <i>et al.</i> , "Induction of Apoptosis by the Low-Affinity NGF Receptor," <i>Science</i> 261:345-348, American Association for the Advancement of Science (1993).
	AT	<u>12</u>	Tartaglia, L.A., <i>et al.</i> , "A Novel Domain within the 55 kd TNF Receptor Signals Cell Death," <i>Cell</i> 74:845-853, Cell Press (1993).

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	AA13						
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	AL13						Yes No
	AM13						Yes No
	AN13						Yes No
	AO13						Yes No
	AP13						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

AR	<u>13</u>	Statutory Declaration of Avi J. Ashkenazi, signed March 14, 2003.
AS	<u>13</u>	Curriculum vitae of Avi Ashkenazi.
AT	<u>13</u>	Copy of provisional U.S. application 60/040,846, inventor Ni <i>et al.</i> , filed March 17, 1997.

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	AA14						
	AB14						
	AC14						
	AD14						
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	AG14						
	AH14						
	AI14						
	AJ14						
	AK14						

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	AL14						Yes No
	AM14						Yes No
	AN14						Yes No
	AO14						Yes No
	AP14						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

AR	<u>14</u>	Copy of provisional U.S. application 60/054,021, inventor Ni <i>et al.</i> , filed July 29, 1997.
AS	<u>14</u>	Copy of U.S. application 08/857,216, inventor Ashkenazi, filed May 15, 1997.
AT	<u>14</u>	Statement of Grounds and Particulars filed in the opposition to Human Genome Sciences, Inc., Australian Patent Application 747635 (67635/98) by Genentech, Inc.

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